Docket No. MCP-274



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicants | : | Joseph Luber |
| Serial No. | : | 09/966,493 |
| Filed | : | 9/28/2001 |
| Title | : | IMMEDIATE RELEASE TABLET |
| Art Unit | : | 1615 |
| Examiner | : | Robert M. Joynes |

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231 on

September 12, 2003
(Date of Deposit)

Sharon E. Hayner
(Name of applicant, assignee, or Registered Representative)

(Signature)

September 12, 2003
(Date of Signature)

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Alexandria, VA 22313-1450

**RESPONSE**

Dear Sir:

This paper is in response to the final Office Action mailed June 12, 2003. Entry of this Response and the accompanying Declaration under 37 C.F.R. §132[1] is respectfully requested as they place the application in better form for allowance or appeal, if necessary. A Notice of Appeal is also enclosed.

Claims 1-20 are pending herein. Claims 1, 17, 18, and 19 are independent. Claim 1 recites an immediate release tablet comprising at least 60 weight % of an active ingredient

[1] A fax copy of the Declaration is enclosed. The original will be sent under separate cover.

and a powdered wax having an melting point greater than about 90° C, said tablet meeting the USP dissolution specifications for immediate release tablets containing said active ingredient.

Claim 17 recites an immediate release tablet comprising at least 60 weight percent of an active ingredient and a powdered wax selected from the group consisting of shellac wax, paraffin-type waxes, polyethylene glycol, and mixtures thereof; wherein said tablet is prepared by direct compression.

Claim 18 recites an immediate release tablet comprising at least 60 weight percent of an active ingredient and a powdered wax selected from the group consisting of shellac wax, paraffin-type waxes, polyethylene glycol, and mixtures thereof; wherein said tablet is substantially free of water-soluble, non-saccharide polymeric binders.

Finally, claim 19 recites an immediate release tablet comprising at least 60 weight percent of an active ingredient and a powdered wax selected from the group consisting of shellac wax, paraffin-type waxes, polyethylene glycol, and mixtures thereof; wherein said tablet is substantially free of hydrated polymers.

All of the pending claims have been rejected as obvious over U.S. Patent No. 5,494,681 to Cuca et al. alone or in combination with additional references. The Examiner argues Cuca teaches a pharmaceutical delivery system comprising an active ingredient, a wax material and a hydrophobic material. The Examiner argues that the amounts specified by applicants overlap with those disclosed by Cuca. The additional references, U.S. Patent No. 5,098,715 to McCabe et al. and U.S. Patent No. 5,681,583 to Conte, are cited to show the use of outer coatings and two active ingredients within the same dosage form, respectively.

The rejections over Cuca are without merit. Cuca teaches the use of a melted wax, while the claimed invention employs powedered wax. Specifically, Cuca discloses a pharmaceutical delivery system comprising a) an active material, and b) a spatially oriented matrix. The spatially oriented matrix in turn comprises (i) a wax core material, and (ii) a regional hydrophobic polymer. Cuca's dosage form is made by melting the wax and the hydrophobic polymer together into a liquid, and then adding the active ingredient thereto. A slurry or dispersion is thereby formed and then cooled. See column 5, line 64 to column 6, line 46. See also all of Cuca's examples.

As previously explained, Cuca's use of melting and melted wax is in contrast to the claimed invention, in which powdered wax is employed. However, in the June 12th Office Action, the Examiner argues that no criticality has been shown by applicants as to the form of

the wax. The Examiner also argues that whether the wax is melted or unmelted is a process difference, and therefore not relevant to applicants' composition claims.

Taking the last point first, each of the independent claims herein recite that the wax is "powdered." Accordingly, the physical state of the wax is an element of the claimed invention. This is not a mere process step.

Regarding the first point, the enclosed Declaration Under 37 C.F.R. §132 of Joseph Luber, an inventor of the subject matter of this application, demonstrates that there is a substantial difference between using melted wax and powdered wax. As set forth in the Declaration, Mr. Luber made a series of tablet containing acetaminopen (APAP) as the active ingredient, wax, and other excipients. Some of the tablets were heated to melt the wax, and some were not. The tablets that were heated (comparative) demonstrated markedly inferior APAP dissolution results compared to the tablets containing powered wax according to the invention. This is, of course, important in that applicants' tablets are immediate release dosage forms.

For these reasons, applicants submit the rejections over Cuca, alone or in combination with McCabe or Conte, should be withdrawn. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

By:_____

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Dated: September 12, 2003